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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,590	10/29/1999	RUSSELL TONY MASELL POULTER	674521-2001.	7513

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/430,590	POULTER ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-14,17,19-21 and 35-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5* is/are allowed.

6)☒ Claim(s) *1-4,10-14,17,19-21 and 35-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on 10/5/2004 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/19/2004 has been entered.

In the response filed 8/19/2004 several claims were amended (claims 5, 10, 12-14, 17, 19 and 35) and several claims to nonelected subject matter were cancelled (claims 7-8, 15-16 and 22-32). Claims 1-5, 10-14, 17, 19-21, 35-51 are pending and under consideration in the instant application. Any rejection of record in the previous office actions not addressed herein is withdrawn. This action is not final.

Drawings

In view of the statement made in the response of 8/19/2004 that none of the drawings submitted on 3/4/2004 comprise color elements, the drawings submitted on 3/4/2004 are accepted.

Claim Objections

Claims 37-42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Each claim recites a limitation of a retrotransposon having percent identity to the POL and LTR region of SEQ ID NO: 3 that is less than 95% when the claim from which they depend recites that the retrotransposon has at least 95% identity to SEQ ID NO: 3.

Claims 44-50 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of these claims recites that the nucleic acid sequence of part (b) of the claim has a minimal sequence identity to the LTR and POL region of the sequence of part (a). Part (b) of claim 19, from which these claims depend, recites the LTR and POL region of pCal as described by GenBank accession number AF007776 and that part (b) consists of the LTR and POL region of SEQ ID NO: 3. Since pCal is taught in the specification as being described by SEQ ID NO: 3 and pCal is also described by GenBank accession number AF007776, it is unclear how these claims further limit claim 19.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10-12, 14, 17, 35-43 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. **These grounds of rejection are maintained for reasons of record in the previous office action and which are repeated below. A response to applicants' arguments follows the rejection.**

Amended claim 12 and dependent claims are directed to an isolated and purified retrotransposon comprising a nucleotide sequence that has at least 95% similarity to (i) SEQ ID NO: 3, (ii) the LTR and POL region of SEQ ID NO: 3 or (iii) to a nucleotide sequence that hybridizes under "stringent" conditions to SEQ ID NO: 3. For each case, the claims read on functional retrotransposable elements. The genus encompassed is a broad one that encompasses a large number of alterations within the sequence described by SEQ ID NO: 3 that allow the resulting nucleic acid to retain function as a retrotransposon. In particular, the limitation of (iii) is egregious in that the recited percent identity is merely to a nucleic acid that hybridizes under undefined "stringent" hybridization conditions to SEQ ID NO: 3, and thus encompasses a much broader genus of nucleic acids than (i) or (ii) that must meet the functional limitation of being a retrotransposon.

Many of the rejected claims comprise the limitation of a "...nucleotide sequence with at least 65% (or 70%, 75%, 80%, 85%, 90%, 95% or 97%) similarity with the LTR and POL region SEQ ID NO: 3...". The rejected claims read on literally any retrotransposon or nucleic acid fragment that comprises a sequence with the recited % similarity to SEQ ID NO: 3. This is an incredibly broad genus of retrotransposons and an even larger genus of nucleic acid fragments. The instant specification provides no basis for envisioning a representative number of embodiments of, for example, retrotransposons that are only similar at a 65% level with only part of the transposon sequence. The instant specification provides no basis for one of skill in the art

to envision nucleic acid fragments that are only 65%-97% similar to the LTR and POL regions of SEQ ID NO: 3 and which retain any sort of retrotransposon activity. Similarly, the specification provides no basis for one to envision embodiments of the claims nucleic acid fragments that retain any of the asserted utilities for the nucleic acid fragments of the invention (e.g. as specific probes for pCal and/or *Candida* species). As pCal appears to be novel in the art, the prior art does not offset the deficiencies of the instant specification with regard to providing a basis for envisioning a sufficient number of specific embodiments as to describe the broadly claimed genus. Therefore, one of skill in the art would have reasonably concluded applicants were not in possession of the claimed invention.

Claims 1-3 are each drawn towards an isolated retrotransposon having a copy number of "between 40-150 or 50-100 copies" of itself per genome. The retrotransposon can be "free" or episomal, or the retrotransposon can be integrated. The retrotransposon can be isolated from fungi or yeast, or more specifically from *Candida albicans*. The broadest embodiments potentially encompass literally any eukaryotic cell type that might harbor a retro-transposable element (e.g. corn, yeast, human, fly, etc.). Even in more specific embodiments, the claims encompass any strain of *Candida* or, more specifically, *Candida albicans*. Each of the claims comprises the functional limitation of between 40 and 150 copies of itself per host cell genome.

The specification teaches one embodiment of the claimed invention (pCal or Tca2) which is found at high copy number in a few particular strains of *C. albicans*. No definitive explanation is provided in the specification for why pCal is maintained at such high copy number in these particular strains of *C. albicans* and not in others. For example, the mechanism could involve some mutation in pCal or a mutation in the particular host, or a combination of mutations

in both the host and pCal. The prior art is of no help in describing a mechanistic rational for maintenance of such high copy numbers because the art does not appear to teach such numbers.

Given the large number of host cell types and retrotransposable elements potentially embraced by the rejected claims and the presence of the functional limitation for high copy number, the presence of only a single relevant example in the specification or prior art meeting the functional limitation for high copy number and the lack of teachings from the specification or prior art as to how such a high copy number is attained by the single relevant example, one of skill in the art would not be able to envision a representative number of specific embodiments of the claimed invention to describe the potentially broad genus of such retrotransposable elements embraced by the rejected claims. Therefore, one of skill in the art would reasonably conclude applicants were not in possession of the claimed invention at the time of filing.

Response to Arguments/Written Description

Applicant's arguments filed on 8/19/2004 have been fully considered but they are not persuasive. The response essentially argues: 1) much of the focus of the rejection is directed to the presence of "stringent hybridization" language and the amendment of the claims to remove the hybridization language obviates this portion of the rejection, 2) independent claim 12 and its dependent claims now recite 95% sequence similarity to SEQ ID NO: 3, 3) Example 14 of the Written Description Guidelines presents a fact patter that is analogous to the instant one and indicates the claims should be allowed, 4) with respect to claims 1-4 related to copy number it is believed the removal of the language directed to hybridization obviates this grounds of rejection.

Removal of the language directed to hybridization of the nucleic acid under stringent hybridization language does in fact obviate the grounds of rejection directed solely to the

hybridization language. With regard to part (a) of claim 12, the argument that the written description guidelines indicate that functional language and 95% identity should be enough to overcome written description problems is accepted for the full length retrotransposon identified by SEQ ID NO: 3. The problem is that claim 12 is also directed to a retrotransposon in part (b) that is only 95% identical to the LTR and POL region of SEQ ID NO: 3. This is not an analogous fact pattern to that recited in Example 14 of the guidelines. Part (b) of claim 12 encompasses a large number of variants of SEQ ID NO: 3, particularly in the regions outside of the LTR and POL of SEQ ID NO: 3, that must retain the functional identity of being a retrotransposon. In this case, the identity to the sequence disclosed by SEQ ID NO: 3 can be far less than 95% since a significant portion of SEQ ID NO: 3 does not fall within the POL and LTR regions.

With respect to the functional limitations of claims 1-3 reciting particular "free DNA copy numbers", there is no description anywhere in the specification as to what changes can be made in SEQ ID NO: 3 such that the resulting retrotransposon necessarily meets the functional limitation. For claims 1-3, the recitation of 95% identity is not sufficient even for part (a) of the claims due to the fact that there is absolutely no structural/functional basis for the skilled artisan to envision which of the many possible retrotransposons that have 95% identity to SEQ ID NO: 3 necessarily meet the further functional limitation of being found as an extrachromosomal DNA molecule having a copy number of 40-150 free copies per cell in *Candida albicans*.

Claims 19-21 & 44-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Claim 19 is directed to a nucleic acid sequence comprising two terminal repeats of the sequence of pCal as described in GenBank accession number AF007776. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. The sequence of pCal as described in the GenBank accession number is essential for practicing the claimed invention. Sequences associated with accession numbers can and do change over time as the sequence databases are updated (e.g. correction of sequencing errors). Also, there is no guarantee that a given database will be available to the public over the entire patent term granted on any claims to issue from the instant application. Therefore, it is essential that the sequence information recited in the claim be presented in the instant application. If the sequence described in accession number AF007776 is already a part of the specification and sequence listing, it would be remedial to simply amend the claim to recite the appropriate sequence number.

If the sequence described by accession number AF007776 is not already part of the specification, applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Claim 13 is vague and indefinite in that the metes and bounds of the term TCa2 are unclear. The specification teaches that TCa2 is the integrated form of pCal and that SEQ ID NO: 3 describes pCal. Upon reading the specification, however, it is unclear whether the term TCa2 is intended to be drawn solely to an integrated form of SEQ ID NO: 3, or alternatively, it can encompass any pCal variant or derivative isolated from any source. For example, pCal is also described in the specification as being functionally characterized as being maintained as numerous free copies of DNA per cell of *Candida sp*. As indicated previously, there is insufficient descriptive support in the specification as filed for all of the possible variants of the species of pCal described by SEQ ID NO: 3 that meet these functional characteristics associated with the term pCal. Thus, if the term TCa2 is intended to encompass all possible variants of pCal, there is likewise an insufficient description in the specification and prior art to provide the skilled artisan a structural/functional basis to envision other embodiments that are broadly encompassed by the term TCa2. If, on the other hand, the term TCa2 is intended to refer only to a single sequence of record in the instant specification, it would be remedial to amend the claim to recite that specific sequence.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 4 & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

Claim 4 is vague and indefinite in that it is unclear how the limitation of being isolated from fungi or yeast further limits the claim. The retrotransposon is what it is with regard to its structure (e.g. nucleic acid sequence) and it is unclear how being isolated from fungi or yeast changes that structure. It would be remedial to amend the claim to clearly recite the structural/functional limitation intended by the limitation "retrotransposon...which is isolated from fungi or yeast."

Claim 13 is vague and indefinite in that the metes and bounds of the term TCa2 are unclear. The specification teaches that TCa2 is the integrated form of pCal and that SEQ ID NO: 3 describes pCal. Upon reading the specification, however, it is unclear whether the term TCa2 is intended to be drawn solely to an integrated form of SEQ ID NO: 3, or alternatively, it can encompass any pCal variant or derivative isolated from any source. It would be remedial to amend the claim to clearly indicate what sequence or sequences are encompassed by the term TCa2.

Allowable Subject Matter

Claims limited to SEQ ID NO: 3 and fragments thereof appear to be allowable over the prior art and meet 112 1st requirements. Claim 5 is allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
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PRIMARY EXAMINER